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Qualification of Unqualified Data

Quality Implementing Procedure ID: OSTI-LLNL-QIP-SIII.4, Rev.0, Mod.0

V. J. Barish, L. A. Gouveia

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QUALIFICATION OF UNQUALIFIED DATA

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1. PURPOSE

This Quality Implementing Procedure (QIP) establishes the responsibilities and process to be used for the qualification of unqualified data. This procedure describes the process and actions to implement the requirements from the OSTI-LLNL Quality Assurance Plan (QAP) which implements the U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) *Quality Assurance Requirements and Description* (QARD), DOE/RW-0333P.

2. SCOPE

This procedure applies to individuals within the Office of Science & Technology and International (OSTI)-Lawrence Livermore National Laboratory (LLNL) Project, and other participants who are responsible for qualification of unqualified numerical/graphical data that are used to develop, calibrate, or directly input process algorithms, formulas, or models used in analysis, technical or model reports. This procedure does not apply to Established Fact data or numerical data obtained from an established/authoritative data source (e.g., National Weather Service, Census Bureau, American Society of Mechanical Engineers, American Society for Testing and Materials, etc.). This procedure has been prepared in accordance with OSTI-LLNL-QIP-5.0, *Preparing the Quality Assurance Plan and Quality/Technical Implementing Procedures.*

3. PROCEDURE

3.1 Planning the Qualification of Unqualified Data

3.1.1 The **Project Manager (PM)** (or designee) shall designate a Qualification Chairperson who is technically competent in the discipline pertaining to the data under consideration to conduct the qualification of data. When the qualification is performed within the Analysis, Technical or Model Report, the report Originator will be the Qualification Chairperson.

3.1.2 The **Qualification Chairperson** shall select additional technical staff members to participate in the data qualification effort.

- At a minimum, the team shall consist of at least two members: the Qualification Chairperson and another technically competent individual. The technical competence of the team members should include the technical areas of the data under consideration.

- For the qualification tasks involving Quality Assurance (QA) program equivalency, the team shall also include the QA Manager (or designee).

- Team members selected should be independent of the data sets to be qualified (i.e., team members did not participate in the acquisition or development of the data sets to be qualified). If independence cannot be achieved, the PM shall provide the rationale for choosing the teammates and provide the method(s) for mitigating any conflict of interest.

3.1.3 Collect background information on the data set(s) to be qualified (e.g., pertinent records associated with the data set(s) to be considered, any available procedures or documentation of data development methodology, data acquisition or development, prior reviews of data).

3.1.4 Review and determine if the data qualification process requires the preparation or revision of a Technical Work Plan (TWP) prepared in accordance with OSTI-LLNL-QIP-2.2, *Planning for Science Activities*, or a Data Qualification Plan (Attachment 1.) In either case, the planning documents shall include the following elements:

A. A listing of the unqualified data set(s).

B. The method(s) of qualification and rationale for selecting the method(s) in accordance with the Considerations for Determining Qualification Methods (Attachment 2), and the Qualification Process Attributes (Attachment 3).

C. Data evaluation criteria are based on the process attributes in Attachment 3. The evaluation criteria provide the topics or considerations on which the Data Qualification Team will be expected to provide judgment.

D. Identification of procedures to be used to control the evaluation process, as applicable (OSTI-LLNL-QIP-SIII.5, *Scientific Analyses*, OSTI-LLNL-QIP-SIII.1, *Technical Reports*; OSTI-LLNL-QIP-SIII.2, *Model Reports*; OSTI-LLNL-QIP-SI.0, *Software Management*; etc.).

E. Obtain the PM's approval for the TWP per OSTI-LLNL-QIP-2.2 or the Data Qualification Plan (Attachment 1).

3.1.5 Obtain a Document Identifier for the Qualification Report in accordance with OSTI-LLNL-QIP-6.0, *Document Control.*

3.2 Conducting a Data Qualification Task

3.2.1 The **Qualification Chairperson** and **Data Qualification Team Members** shall:

A. Complete the data qualification task in accordance with the Data Qualification Plan (Attachment 1), or the TWP and applicable procedures.

B. Provide the preliminary data to the Technical Data Coordinator for submittal to the Technical Data Management System (TDMS) in accordance with

OSTI-LLNL-QIP-SIII.3, *Submittal and Incorporation of Data to the Technical Data Management System.*

If the qualification is being conducted within a work product (i.e., Analysis, Technical or Model Report) and 1) the qualification is "providing a desired level of confidence that the data are suitable for their intended use," and 2) the intended use is only for that work product, then these data shall not be submitted to the TDMS.

C. Provide documentation that recommends superseding data sets and/or adding new data sets that result from the qualification task in accordance with OSTI-LLNL-QIP-SIII.3, as required.

3.3 Documentation, Review and Check of Results

3.3.1 The Qualification Chairperson or Data Qualification Team Members shall:

A. Document the results of the data qualification task. Data qualification tasks may be documented in a Data Qualification Report or as a part of a technical or model report prepared in accordance with OSTI-LLNL-QIP-SIII.1 or OSTI-LLNL-QIP-SIII.2. The Data Qualification Report, technical, or model report shall include, as applicable, a discussion of the following items:

1. The data set(s) for qualification.
2. The method(s) of qualification selected and rationale.
3. Evaluation criteria.
4. An evaluation of the technical correctness of the data, as applicable.
5. Data generated by the evaluation, if applicable.
6. The evaluation results.
7. A conclusion for/against changing the qualification status of the data based on the team's judgment in response to the evaluation criteria and the evaluation results. Refer to the TWP or the Data Qualification Plan (Attachment 2), as appropriate.
8. The rationale for abandoning any of the qualification methods, if appropriate.
9. A discussion of any limits or caveats that should be considered by potential users of the data.
10. Identification of any supporting information used in the qualification effort by the appropriate reference identifier (e.g., Data Tracking

Number [DTN], accession number, Technical Information Center [TIC] catalog number, etc.).

11. Reference to the TWP or the Data Qualification Plan (Attachment 1). Deviations to the plan should be documented and justified in the report.

B. Forward the Data Qualification Report, prepared in accordance with this procedure, to the Technical and QA Reviewer and Checker assigned by the Deputy PM. When the data qualification report is prepared in accordance with OSTI-LLNL-QIP-SIII.1 or OSTI-LLNL-QIP-SIII.2, the reviews and checking shall be conducted in accordance with these procedures.

3.4 Review of the Data Qualification Report

3.4.1 PM/DPM (or designee):

A. Assign a Technical Reviewer, other than the Qualification Chairperson or Data Qualification Team Members, who has adequate qualifications to have originated the Data Qualification Report. The review shall be conducted in accordance with OSTI-LLNL-QIP-6.1, *Document Review*.

B. Assign a QA Reviewer, other than the Originator, who has adequate qualifications to perform a quality review of the Data Qualification Report for compliance to applicable procedural requirements and for incorporation of appropriate QA requirements, in accordance with OSTI-LLNL-QIP-6.1.

C. Assign a Checker(s), other than the Originator, to check the Data Qualification Report. The technical Checker assigned to check the Data Qualification Report shall have adequate education, training and experience to understand/evaluate the contents of the Data Qualification Report being checked.

3.4.2 Technical/QA Reviewer:

A. An independent, Technical Reviewer shall conduct a technical content review in accordance with OSTI-LLNL-QIP-6.1. The Technical Review may be completed before Checking, or performed concurrently, as directed by the PM/DPM (or designee). The Technical Reviewer shall conduct an overall assessment of the technical quality of the document, including the document's technical adequacy, correctness, completeness, accuracy, applicability to the issues being addressed, and compliance with requirements provided in the governing procedure. Additional technical review criteria may be identified on the Review Record, as deemed appropriate by the PM/DPM (or designee).

B. The QA Reviewer shall conduct a QA content review in accordance with OSTI-LLNL-QIP-6.1. The QA Review may be performed concurrently with Checking or after Checking, as directed by the PM/DPM (or designee). The QA Reviewer shall ensure that quality requirements are adhered to.

Additional QA review criteria may be identified on the Review Record, as deemed appropriate by the PM/DPM (or designee).

3.4.3 Checker:

If the qualification is documented in a Data Qualification Report in accordance with this procedure, ensure the following:

A. The content of the report is technically adequate, complete, and correct, and the documentation has been prepared in accordance with this procedure and the applicable TWP or Data Qualification Plan.

B. Software, if used, is identified by a Software Tracking Number (STN), title, revision/version number, computer type, is adequate for the intended use, was used within the range of validation and has been obtained, controlled, and documented in accordance with OSTI-LLNL-QIP-SI.0, or if previously developed for the Yucca Mountain Project (YMP) has been obtained, controlled, and documented in accordance with applicable YMP procedures.

C. Data were correctly selected, identified in the report documentation, cited and incorporated, and are appropriate for use.

D. Uncertainties and restrictions are discussed within the report documentation.

E. The assumptions, constraints, bounds, or limits on the data are identified in the documentation.

F. The referencing is thorough, accurate, and complete, including appropriate tracking numbers (e.g., records accession numbers, TIC numbers, and/or DTNs).

G. Data cited are verified to be the same as those in the TDMS.

H. Document comments and comment resolution on the hard copy or using the Review Record and Comment Sheet from OSTI-LLNL-QIP-6.1.

3.4.4 Qualification Chairperson:

Following resolution of the Technical/QA Reviewer and Checker comments, forward the Data Qualification Report to the PM for approval.

3.4.5 Project Manager (or designee):

Review and approve the Data Qualification Report or the Technical/Model Report where the data qualification was documented.

3.4.6 Qualification Chairperson:

A. If the qualification is being conducted within a work product (i.e., Technical or Model Report.) and 1) the qualification is "providing a desired level of

confidence that the data are suitable for their intended use," and 2) the intended use is only for that work product, then no action is required under OSTI-LLNL-QIP-SIII.3.

B. If the qualification is being conducted within a Data Qualification Report, evaluate the preliminary data submittal (per Section 3.2.1) and provide the Technical Data Coordinator with an updated list of qualified data sets and supporting information, in accordance with OSTI-LLNL-QIP-SIII.3, as appropriate.

C. Prepare and submit the records to the Records Coordinator in accordance with Section 4.

D. Submit the approved Data Qualification Report to the Records Coordinator in accordance with OSTI-LLNL-QIP-6.0, *Document Control.*

4. RECORDS

The records listed below shall be collected and submitted to the Records Coordinator for submittal to OSTI/OCRWM in accordance with OSTI-LLNL-QIP-17.0, *Records Management,* as individual records or included in a records package, as specified. If qualification of data is conducted in a Technical or Model Report, records shall be submitted in accordance with the governing procedure for the product.

4.1 QA Records

For a Data Qualification Report subject to the requirements of the QAP:

Data Qualification Report Records Package:

Data Qualification Plan

- Data Qualification Report
- Checker review documentation

OSTI-LLNL-QIP-6.1 review documentation of Data Qualification Report

4.2 Non-QA Long-Term Records

Review Drafts.

4.3 Non-QA Short-Term Records (Three Years or Less Retention)

None.

5. RESPONSIBILITIES

5.1 The **Project Manager (PM)** (or designee) is responsible for assigning the Data Qualification Chairperson (if other than the Technical or Model Report Originator); for the final disposition of disputed comments; and the approval of the Data Qualification Report.

5.2 The **PM/DPM** (or designee) is responsible for appointing Checkers/Technical/QA Reviewers on the basis of education, training and experience. The Deputy PM (or designee) is also responsible in assigning specific review criteria as deemed appropriate.

5.3 The **Quality Assurance (QA) Manager** (or designee) is responsible for participating in the Data Qualification Team when the qualification tasks involve QA program equivalency.

5.4 **Qualification Chairperson (Analysis, Technical or Model Report Originator)** and **Data Qualification Team Members** are responsible for conducting the data qualification as described in this procedure.

5.5 The **Checker** is responsible for performing checks for technical issues and compliance with procedural controls. The Checker shall have adequate education, training and experience to understand/evaluate the contents of the technical report being checked. A Checker shall not have participated in the authorship of the portion of the document (e.g., chapter) under his/her check.

5.6 The **Technical Reviewer,** a technically competent individual, other than the Qualification Chairperson or the Data Qualification Team Members, is responsible for reviewing the Data Qualification Report, providing written comments on the Comment Sheet or draft documentation, and evaluating/accepting Originator responses. Comments shall be returned to the Originator in a timely manner.

5.7 **QA Reviewer(s)** is responsible for reviewing the Data Qualification Report, providing written comments on the Comment Sheet or attached documentation, and evaluating/accepting Originator responses. Comments shall be returned to the Originator in a timely manner.

6. ACRONYMS AND DEFINITIONS

6.1 Acronyms

DI	Document Identifier
DOE	U.S. Department of Energy
DTN	Data Tracking Number
EPA	Environmental Protection Agency
LLNL	Lawrence Livermore National Laboratory
NRC	U.S. Nuclear Regulatory Commission
OCRWM	Office of Civilian Radioactive Waste Management

OSTI	Office of Science & Technology and International
PI	Principal Investigator
PM	Project Manager
QA	Quality Assurance
QAP	Quality Assurance Plan
QARD	Quality Assurance Requirements Description
QIP	Quality Implementing Procedure
RC	Records Center
TDMS	Technical Data Management System
TIC	Technical Information Center
TWP	Technical Work Plan
YMP	Yucca Mountain Project

6.2 Definitions

Corroborating Data: Data that are used to support or substantiate other data . The use of corroborating data has no impact on the qualification status of the supported data because they are not used in the direct formulation of the arguments or datasets.

Data (Collected): Factual information obtained from investigation activities such as sample collection, physical measurements, testing, and analyses, both in the field and in a laboratory (QARD).

Established Fact: Information accepted by the scientific and engineering community as established fact (e.g., engineering handbooks, density tables, gravitational laws, etc.) (QARD).

Preliminary Submittals: Data acquired or developed using approved procedures that have not received a technical review (that establishes and documents the technical validity of the data.

Qualification of Data: A formal process intended to provide a desired level of confidence that data are suitable for their intended use (QARD).

Qualified Data: Data collected under an approved QA program that meets the requirements of 10 CFR Part 63, Subpart G, or a previously implemented 10 CFR 60 QA program (i.e., qualified from origin), or unqualified data that have undergone the qualification process.

Subject Matter Expert: An individual recognized by his or her peers as an authority on a specific topic (QARD).

Technical Assessment: Used for data qualification purposes, a technical assessment is an evaluation of the technical merit of unqualified data against established criteria (QARD).

Unqualified Data: Data not collected under an approved QA program that meets the requirements of 10 CFR Part 63, Subpart G, or a previously implemented 10 CFR 60 QA program.

7. REFERENCES

10 CFR 60, Energy: Disposal of High-Level Radioactive Wastes in Geologic Repositories

10 CFR 63, Energy: Disposal of High-Level Radioactive Wastes in a Geologic Repository at Yucca Mountain, Nevada

Quality Assurance Requirements and Description, DOE/RW-0333P

OSTI-LLNL-QIP-2.2, *Planning for Science Activities*

OSTI-LLNL-QIP-5.0, *Preparing the Quality Assurance Plan and Quality/Technical Implementing Procedures*

OSTI-LLNL-QIP-6.0, *Document Control*

OSTI-LLNL-QIP-6.1, *Document Review*

OSTI-LLNL-QIP-17.0, *Records Management*

OSTI-LLNL-QIP-SI.1, *Software Management*

OSTI-LLNL-QIP-SIII.1, *Technical Reports*

OSTI-LLNL-QIP-SIII.2, *Model Reports*

OSTI-LLNL-QIP-SIII.3, *Submittal and Incorporation of Data to the Technical Data Management System*

OSTI-LLNL-QIP-SIII.5, *Scientific Analyses*

8. ATTACHMENTS

Attachment 1- Data Qualification Plan
Attachment 2- Considerations for Determining Qualification Methods
Attachment 3- Qualification Process Attributes

9. REVISION HISTORY

2/25/05 Revision 0, Modification 0:

Initial Issue

10. APPROVALS

Preparer: Leigh Gouveia — Date: 2/25/05

Technical Reviewer: QINHONG HU — Date: 2/25/05

QA Reviewer: VICTOR J. BARISH Sr. — Date: 2/25/05

Project Manager: DAVID B. McCALLEN — Date: 2/25/05

Lawrence Livermore National Laboratory	**OSTI-LLNL** **Data Qualification Plan**	QA:QA 1. Page 1 of

SECTION I. PLANNING INFORMATION
Data Qualification Plan Title:
Data Qualification Plan DI:
SECTION II. PROCESS PLANNING REQUIREMENTS
1. List of Unqualified Data to be Evaluated
2. Type of Data Qualification Method(s) [Including rationale for selection of method(s) (Attachment 3) and qualification attributes (Attachment 4)]
3. Data Qualification Team
4. Data Evaluation Criteria
5. Identification of Procedures Used

SECTION III. APPROVAL		
Qualification Chairperson (Printed Name)	Qualification Chairperson (Signature)	Date
Project Manager (Printed Name)	Project Manager (Signature)	Date

EXAMPLE

CONSIDERATIONS FOR DETERMINING QUALIFICATION METHODS

One or a combination of methods identified below can be used to qualify data. Methods 1, 2, and 3 shall include an initial evaluation of the data quality and correctness. The Data Qualification Team shall evaluate the data by comparing the methods used to plan, collect, and analyze the data against generally accepted scientific or engineering practices. If the evaluation determines the data to be adequate, proceed with implementation of the Data Qualification Methods 1, 2, and/or 3, otherwise porceed with implementation of the Data Qualification Methods 4 and 5.

1. Equivalent QA Program

The Equivalent QA Program approach may be used for the qualification of unqualified data when the acquisition, development, or processing of data can be demonstrated to be functionally equivalent (i.e., similar in scope and implementation) to the general process requirements of the QARD. The employed practices or procedures must demonstrate industry acceptable scientific, engineering, or administrative practices or processes with appropriate documentation as defined in this procedure.

The following is a condition for an Equivalent QA Program approach:

Information or documentation is available for the Data Qualification Team to assess the functional equivalence of the data-gathering process to applicable QARD concepts as identified by the attributes in Attachment 3 (e.g., attributes 1, 2, 5, 6, 8, and/or 11).

Action to be Taken: Review available information and records with the evaluation criteria and document that they define a process that is functionally equivalent to applicable QARD requirements.

2. Corroborating Data

The Corroborating Data approach may be used when data comparisons can be shown to substantiate or confirm parameter values. The corroborating data qualification process may include comparisons of unqualified to unqualified data, as well as unqualified to qualified data with appropriate compliance documentation as defined in this procedure.

The following are conditions for the use of the Corroborating Data:

a) Corroborating Data are available for comparison with the unqualified data set(s).

b) Inferences drawn to corroborate the unqualified data can be clearly identified, justified, and documented.

Action to be Taken: Identify the data set(s) that will be used to corroborate the unqualified data set(s). Identify, justify, and document the rationale for using these data set(s) and the inferences drawn to corroborate the unqualified data.

3. Confirmatory Testing

The Confirmatory Testing approach may be used when previous test results are non-verifiable as a result of questionable testing methodology or a lack of applicable documentation. Consideration must be given to confirmatory testing resources and schedule requirements to ensure confirmatory testing is a viable qualification option within the project's funding and time constraints. Confirmatory test results must demonstrate direct correlation to previous test results; however, data extrapolation is acceptable within the limits defined in the compliance documentation defined in this procedure.

The following are conditions for a Confirmatory Testing approach:

a) Funding and schedule time are available.
b) Similar test conditions are prescribed.
c) Test result correlation or extrapolations are applicable.

Action to be Taken: Evaluate test funding and schedule requirements to determine the availability of resources and time to complete the testing (subject to the approval of the PM/DPM/OSTI as applicable). Ensure similar test and data reduction conditions can be established to replicate previous test results. If it is determined that resources and time permit confirmatory testing, and similar test and data reduction conditions can be replicated, implement the confirmatory testing process and document the applicability of the test result correlation or extrapolations with the documentation defined in this procedure.

4. Peer Review (subject to the approval of the PM/DPM/OSTI as applicable)

If Peer Reviews are used, the appropriate QIP shall be developed prior to initiating the Peer Reviews.

The following are examples of conditions for a Peer Review approach:

a) The other four methods cannot be applied or are inappropriate.

b) The adequacy of information of the suitability of the implementing documents and methods essential to meet specified objectives cannot be established through testing, alternate calculations, or reference to previously established standards and practices.

c) Critical interpretations have been made or conclusions have been drawn in the face of significant uncertainty.

d) Novel, or beyond the state-of-the-art, testing or analyses have been utilized.

e) Detailed technical criteria or standard industry practices or procedures are not available.

f) Test results are not reproducible.

g) Data or interpretations are questionable or ambiguous.

h) Data adequacy is questionable, such as data may not have been collected in conformance with an established 10 CFR 60 Subpart G QA program or equivalent program.

Action to be Taken: Evaluate the data acquisition and development approach. Summarize and evaluate the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions in data being qualified, as applicable. Compile supporting records and present the team's evaluation and supporting records package to a Peer Review Panel. The Peer Review Panel shall review the evaluation and supporting documentation, assess the adequacy of the data being qualified, and document their conclusions in a report in accordance with the applicable procedure. In this method, the Data Qualification Team's evaluation and the Peer Review Panel Report will be the documentation of the qualification process.

5. Technical Assessment

The Technical Assessment approach may be used when it is determined that an independent evaluation of the data by a Subject Matter Expert is needed to raise the confidence of the data to a proper level for the intended use.

Either of the following conditions could require using the Technical Assessment approach:

a) The confidence in the data is in question because data collection procedures are unavailable for review, or the procedures used are not adequate.

b) Documentation or proof of proper data acquisition is unavailable for review.

Actions to be Taken: Conduct an independent evaluation of the data and available documentation by a Subject Matter Expert who is independent from the data collection or data reduction process. It is required that documentation be traceable to the original source of the data (it is noted that the original source can be a scientific journal, publication, etc.) and that checking, review, and approval of the data (and data use) can be conducted without recourse to the Subject Matter Expert that is qualifying the data. The Technical Assessment should include one or a combination of the following:

1) Determination that the employed methodology is acceptable. A discussion and justification that the data collection methodology used was appropriate for the type of data under consideration (used appropriate equipment, typical of scientific and industry collection methods, etc.).

2) Determination that confidence in the data acquisition or developmental results is warranted. A discussion and justification that the data acquisition and/or subsequent data development (e.g., reduction or extrapolation) discussed in

source documentation was appropriate for the type of data under consideration. This could include assurances that processes were conducted by qualified professionals; data were collected under proper environmental conditions; collected results and/or data development are appropriate, reasonable, and suitable for their intended use; etc.

3) Confirmation that the data have been used in similar applications. A discussion and documentation that the data have been used in applications that are similar to those for which the data will be used. Past applications could include data used by the U.S. Nuclear Regulatory Commission (NRC) or Environmental Protection Agency (EPA) (or their subcontractors) in technical evaluation reports, licensing proceedings, or safety evaluation reports; by nationally/internationally recognized scientific organizations (e.g., International Atomic Energy Agency, International Radioactive Waste consortiums, etc.); or by the scientific community, including publications, peer reviews, etc.

QUALIFICATION PROCESS ATTRIBUTES

The process of qualifying unqualified data may consist of any of the five methods or a combination of methods identified in Attachment 2. It is not expected that all of these attributes will need to be examined for each data set under review. In certain cases, replication of test results, for example, could provide confidence in data in lieu of specific QA measures such as independent audits. Attributes that may need to be considered in the qualification process are:

1. Qualifications of personnel or organizations generating the data are comparable to qualification requirements of personnel generating similar data under the approved 10 CFR 60, Subpart G, program.

2. The technical adequacy of equipment and procedures used to collect and analyze the data.

3. The extent to which the data demonstrate the properties of interest (e.g., physical, chemical, geologic, mechanical).

4. The environmental conditions under which the data were obtained if germane to the quality of data.

5. The quality and reliability of the measurement control program under which the data were generated.

6. The extent to which conditions under which the data were generated may partially meet 10 CFR 60, Subpart G.

7. Prior uses of the data and associated verification processes.

8. Prior peer or other professional reviews of the data and their results.

9. Extent and reliability of the documentation associated with the data.

10. Extent and quality of corroborating data or confirmatory testing results.

11. The degree to which independent audits of the process that generated the data were conducted.

12. The importance of the data to showing that the proposed U.S. Department of Energy repository design meets the performance objectives of 10 CFR 60.